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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-Day comment request Investigational Agent Accountability Record Forms and International Investigator Statement in the Conduct of Investigational Trials for the Treatment of Cancer (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Charles Hall, Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Diagnosis and Treatment, National Cancer Institute, 9609 Medical Center Drive, Bethesda, Maryland, 20892 or call non-toll-free number (240) 276-6575 or E-mail your request, including your address to: HallCh@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on September 14, 2021 (Vol. 86 FR 51168) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Investigational Agent Accountability Record Forms and International Investigator Statement in the Conduct of Investigational Trials for the Treatment of Cancer (National Cancer Institute), 0925-0613, Expiration Date 3/31/2022, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Food and Drug Administration (FDA) require Investigational New Drug Application (IND) sponsors to maintain adequate records on the shipment and disposition of agents to investigators. The agent accountability effort for National Cancer Institute/Division of Cancer Treatment and Diagnosis/Cancer Therapy Evaluation Program (NCI/DCTD/CTEP) is managed by the Pharmaceutical Management Branch (PMB) at CTEP. The Investigational Agent Accountability Records (a.k.a. Drug Accountability Record Forms - DARF) are used to provide a standardized method of tracking of agent disposition across all institutions participating in trials for which the NCI provides agent. Institutional auditors verify information on the agent accountability forms for compliance. In addition, PMB staff

review Investigational Agent Accountability Record Forms against records maintained in PMB systems to ensure there is no inappropriate use or diversion of investigational agents. Additionally, the International Investigator Statement (IIS) will be used by non-U.S. investigators, that are unable to sign the FDA 1572 (OMB No. 0925-0753, Expiration 05/31/2024) to attest compliance with applicable country-specific regulations.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden are 4,831 hours.

Estimated Annualized Burden Hours

Form Name	Category of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hours
A1: Investigational Agent Accountability Record Form (DARF)	Individuals	760	20	4/60	1,013
A2: Investigational Agent Accountability Record for Oral Agents Form (DARF-Oral)	Individuals	2,280	20	4/60	3,040
A3: Electronic Agent Accountability Record Form (eDARF)	Individuals	760	20	1/60	253
A4: International Investigator Statement (IIS) (Initial Response)	Individuals	2,100	1	15/60	525
Totals		**5,900**	**78,100**		**4,831**

Dated: November 18, 2021.

Diane Kreinbrink,

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National Institutes of Health.

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